DETAILED ACTION

Response to Arguments

1. The response filed on **1/13/11** has been entered.

2. Applicant's arguments filed 1/13/11 have been fully considered but they are not deemed to be persuasive.

3. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

4. Claims 1- 3 and 6-26 are pending in this office action. Claims and 12-22 are withdrawn due to restriction requirement . Claims 1-3, 6-11 and 23-26 are rejected in this office action.

5. Bischoff is withdrawn from the 35 USC 103 rejection as Applicant correctly argued that Bischoff is not a prior art.

New Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the

> invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

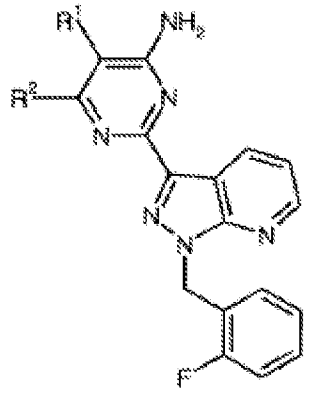
The factual inquiries set forth in *Graham* v. *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-3, 6-11 and 23-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Alonso-Alija et al. (US Patent 7,173,037) in view of Hilleman et al. Pharmacotherapy: Volume 21, Issue 11, pp. 1415-1421 (2001).

Alonso-Alija et al. teach a composition comprising a pharmaceutical active ingredient component A that is a direct stimulator of soluble guanylate cyclase having the same chemical structure as the recited formula I (see abstract), wherein



Recited compound of Formula I	Prior Art compound	SAME
R^1	R^1	$NR^3(=O)OR^4$
R^2	R^2	Hydrogen or NH_2
R^3	R^3	(C1-C4)-alkyl
R^4	R^4	(C1-C6)-alkyl

as required by instant claims 1-3 (see col. 2, lines 23-65 and col. 3, lines 1-23 (as required by instant claim 3). The composition of Alonso includes other active agents to be administered in combination with the compounds of formula I for use as medicaments for the treatment of cardiovascular disorders, such as high blood pressure, atherosclerosis (i.e., conditions in which fatty material collects along the walls of arteries, see col. 8, lines 56-65) and which includes nitric oxide donors (which releases nitric oxide in treatment, see col. 9, lines 45-55).

Intrinsically the compound/composition of formula 1 (component A) may be "permitted" to be administered separately, simultaneously with the NO donor compound or sequentially (as required by instant claims 24-25).

However Alonso-Alija et al. fail to teach that the active ingredient of component B is a HMG-CoA inhibitor (i.e., atorvastatin, cerivastatin; as required by instant claims 1, 8-11 and 26).

Hilleman et al teaches HMG-CoA inhibitors reduce coronary revascularization and cardiovascular mortality (see as under result sec.).

Although Alonso-Alija et al. failed to specifically teach combination of HMG-CoA inhibitors with their compounds, one of ordinary skill in the art would have been motivated to include other medicaments used for treating fatty deposit along the walls of the artery with a HMG-CoA reductase because it is known in the art that HMG-CoA inhibitors reduce coronary revascularization and cardiovascular mortality

One of ordinary skill in the art would have been motivated to add HMG-CoA reductase for the treatment of cardiovascular disorders, such as high blood pressure, atherosclerosis (i.e., conditions in which fatty material collects along the walls of arteries, see col. 8, lines 56-65) because Alosnso-Alija teaches that other medicaments based on the type of cardiovascular disease being treated with a reasonable expectation of success that the use of any of the HMG-CoA reductase inhibitors will reasonable result in success..

Additionally it is known in the art that treating combining medication for the treatment of a disease would normally give additive effect absent factual evidence. Thus, the claimed invention was prima facie obvious.

7. No claim is allowed.

8. Any inquiry concerning this communication or earlier communications from the Examiner should be directed to SHIRLEY V. GEMBEH whose telephone number is (571)272-8504. The examiner can normally be reached on 8:30 -5:00, Monday- Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, BRANDON FETTEROLF can be reached on 571-272-2919. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/S. V. G./
Examiner, Art Unit 1618
5/18/11
/Brandon J Fetterolf/
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